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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,567	07/06/2001	Carlos Plata-Salaman	ORT-1453	4092

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EXAMINER
FONDA, KATHLEEN KAHLER

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 07/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,567	PLATA-SALAMAN ET AL.	
	Examiner	Art Unit	
	Kathleen Kahler Fonda, Ph.D.	1623	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection made in a prior Office action and not expressly repeated herein is withdrawn in view of Applicant's arguments and/or amendments.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 1 is indefinite because although it now recites a step of administration, there is no requirement that the mammal receiving the administration be the one in which treatment or prevention is to be accomplished. Thus the scope of the claim is not clear. In order to overcome this rejection, the Examiner suggests amending the claim to read in pertinent part, "treating or preventing the development of Type II diabetes mellitus in a mammal comprising administering to [a] said mammal." Claims 5 and 15 are similarly indefinite, and should be similarly amended. Claims 10 and 20 are similarly indefinite; "in mammals" should be replaced with --in a mammal-- and "a mammal" should be replaced with --said mammal--.

Claims 1, 2, 10, 11, 15, 16, 20, and 21 are again rejected, as set forth in the Office action of 03-21-03, under 35 U.S.C. 102(a) and/or (b) as being anticipated by EDWARDS *et al.* (U).

Applicant's arguments filed 06-20-03 have been fully considered but they are not persuasive.

Applicant argues that EDWARDS is concerned with treating painful diabetic neuropathy, and does not teach or suggest treating or preventing type II diabetes. Applicant also takes issue with the Examiner's statement that the patients of EDWARDS suffered from impaired oral glucose tolerance or type II diabetes.

It is the Examiner's position that "treating . . . Type II diabetes mellitus" as recited in claim 1 is broad enough to encompass treating symptoms of that disease, such as painful neuropathy. As indicated in the previous Office action, because EDWARDS states that 26 patients ages 36 to 77 years were treated, it is reasonable to conclude that at least some of the 26 patients had Type II or adult-onset diabetes. This is especially considered to be so because those of ordinary skill in the art know that Type II diabetes is by far more common than Type I. According to the American Diabetes Association (see

http://www.diabetes.org:80/main/application/commercewf?origin=*.jsp&event=link(B), accessed by the Examiner on July 9, 2003), "Approximately 90-95% (16 million) of Americans who are diagnosed with diabetes have type 2 diabetes." Because at least some of the EDWARDS patients have Type II diabetes, they have impaired oral glucose tolerance (claim 10), and are afflicted with defective insulin sensitivity (claim 20); these are known characteristics of Type II diabetes, as acknowledged at pages 2-3 of the specification. Furthermore, even if none of the EDWARDS patients had Type II diabetes, which the Examiner does not concede, claims 1, 2, 15, and 16 are still anticipated because they read on prevention and do not require the patient to be suffering from any disease at all.

Claims 1-9 and 15-19 are again rejected, as set forth in the Office action of 03-21-03, under 35 U.S.C. 102(b) as being anticipated by SHANK (CA).

Applicant's arguments filed 06-20-03 have been fully considered but they are not persuasive.

Applicant argues that SHANK does not discuss Type II diabetes or Syndrome X, and that there is no direct correlation between obesity and either of these conditions. Thus Applicant concludes that the reference is no anticipatory.

These arguments are not convincing because the reference need not mention Type II diabetes or Syndrome X at all in order to anticipate. All that is needed is that the reference teach what Applicant now claims. SHANK teaches administration of a compound of the claims, in amounts of the claims, to a mammal of the claims. As Applicant correctly points out in the fifth paragraph on page 10 of the Remarks of 06-20-03, this rejection is made as to the preventive aspect of the claims. That is, the mammalian recipient is not afflicted Type II diabetes or Syndrome X prior to the administration. The Examiner agrees with Applicant that there is no direct correlation between obesity and either of these conditions, and there need not be. The steps of the method are old, and discovery of a new benefit for an old process does not render the old process patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Merely because SHANK did not have one of Applicant's purposes in mind when the drug was administered does not alter the drug's physiological activity. In the context of an anticipation rejection, the Federal Circuit stated, "Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." Mehl/Biophile Int'l Corp. v. Milgraum, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999). Thus, because SHANK

deliberately intended the disclosed administration within the scope of the claims, and because the necessary result was prevention as claimed, the instant claims are anticipated regardless of whether or not SHANK appreciated that result.

No claim is allowed. However, claims 12-14 and 22-24 appear to be free of the prior art. No prior art of record teaches or suggests administration of the therapeutic amounts as recited in these claims. If claims 12-14 and 22-24 were drafted in independent form so as to avoid the indefiniteness issue raised above, it appears that they would be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will

expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Technology Center 1600 by facsimile transmission. The number of the fax machine for official papers in Technology Center 1600 is (703) 308-4556. Any document submitted by facsimile transmission will be considered an official communication unless the cover sheet clearly indicates that it is an informal communication.

INTERNET INFORMATION: Secure and confidential access to patent application status information is now available; see http://www.uspto.gov/ebc/index.html for more information. Also, http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm may be used to pay patent maintenance fees, pay non-filing application fees, and maintain USPTO deposit accounts.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kathleen Kahler Fonda, at telephone number (703) 308-1620. Examiner Fonda can generally be reached Monday through Friday from 7:30

a.m. until 4:00 p.m. If the Examiner cannot be reached, questions may be addressed to Supervisory Patent Examiner James O. Wilson at (703) 308-4624. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Kathleen Kahler Fonda, Ph.D., J.D.
Primary Examiner
Art Unit 1623